DEFICIENCY REPORTING AND CORRECTING

Purpose

This Air Quality Group procedure describes the process for identifying and correcting deficiencies within the group.

Scope

This procedure applies to all personnel in the group who identify, evaluate, or correct deficiencies.

In this procedure

This procedure addresses the following major topics:

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Hazard Control Plan

The hazard evaluation associated with this work is documented in HCP-ESH-17-Office Work.

Signatures

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01/26/04

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General information about this procedure

Attachments

This procedure has the following attachments:

Number	Attachment Title	No. of pages
1	Deficiency Report	2

History of revision

This table lists the revision history and effective dates of this procedure.

Revision	Date	Description of Changes
0	8/4/95	New document; supersedes HS-9-RAEM-QP-06 "HS-9 RAEM Procedure for Control and Reporting of Nonconformances."
1	8/13/99	Clarify definition of deficiency to include external requirements.
2	1/8/02	Reformatted, words added to include processes, and reference added to deficiency database.

Who requires training to this procedure?

The following personnel require training before implementing this procedure:

- group leader
- all group team leaders
- QA team members
- responsible managers
- responsible individual assigned to perform corrective actions

Not required to train to this procedure are:

- originators of Deficiency Reports

Personnel previously trained to Revision 1 do not require re-training to Revision 2.

Training method

The training method will be "**self-study**" (reading) and will be documented in accordance with the procedure for training (ESH-17-024).

General information, continued

Definitions specific to this procedure

Corrective Action: Measures taken to rectify deficiencies and to preclude repetitions.

References

The following documents are referenced in this procedure:

- ESH-17-024, "Personnel Training"
- 40 CFR 61, "National Emissions Standards for Hazardous Air Pollutants"

Note

Actions specified within this procedure, unless preceded with "should" or "may", are to be considered mandatory guidance (i.e., "shall").

Identifying deficiencies

What is a deficiency?

ESH-17 must comply with external requirements in state, federal, and LANL laws, regulations, and requirements. The group also imposes additional requirements on itself as given in group program plans, project plans, and procedures. A deficiency occurs when one of these requirements is not met. The group has adopted the word "deficiency" to replace other commonly used terms such as finding, condition adverse to quality, and nonconformance.

Examples include: failure to follow a procedure as required, failure to document training before performing a procedure, omission of requirements from a procedure or process, and an equipment or process failure that results in loss of required data or samples.

Why document deficiencies?

A deficiency identification, tracking, and correcting system is required by 40 CFR 61. Documenting all deficiencies allows the group to spot trends and recurring problems. Lessons can be learned from previous problems. Possible resolutions to recurring deficiencies include changing the process to minimize the variability that causes deficiencies, or evaluating the need for the requirement in order to eliminate it, if possible. Documenting deficiencies also serves to elevate a problem to management attention so, if appropriate, more resources can be made available for fixing and preventing the problem.

Deficiencies are *not* intended to be punitive and are *never* to be initiated as retaliation against an individual. The principle is to identify the root causes and fix the system that caused the error, not to punish the mistake or failure.

When deficiencies are noted

Any **employee**, when deficient conditions are noted, should complete Part 1 of a Deficiency Report (Attachment 1) by

- describing the condition, and
- noting the specific requirement not being met (when known).

After completing the form, sign it and forward to a group QA team member.

If the deficient condition can be quickly and easily corrected (for example, a circuit breaker that has tripped), the condition may be corrected immediately.

If the problem poses immediate hazards

If the violation or condition is deemed significant by the employee, the **employee** must take immediate action to stop work and/or notify the supervisor responsible for the deficient work or condition. Heed the laboratory stop work requirements (given in the Laboratory ES&H Policy), if appropriate.

Identifying deficiencies, continued

Audit findings

For deficiencies or findings identified during any audits or assessments of the group, the **QA team** will initiate a Deficiency Report by entering the finding description from the audit report onto a Deficiency Report form.

This allows all problems found in the group or division, even if found by outside auditors, to be tracked and corrected by the same system.

Logging and checking the Deficiency Report

Determine if duplicate

After receiving a Deficiency Report, the **QA team** reviews it to determine if the deficiency has already been identified. If the deficiency is a duplicate, return the Deficiency Report to the originator with an explanatory note. Duplicate Deficiency Reports receive no further action. (As a courtesy, the originator of the duplicate should be informed, after the deficiency is closed, of the final resolution of the original deficiency.)

Check requirement citation

The **QA team** reviews the Deficiency Report to verify if the deficient condition is a violation of a referencable and applicable regulation or requirement. Consult with an appropriate technical or subject matter expert, if necessary. After the review, the **QA team** completes Part 2 of the Deficiency Report.

If the requirement or regulation is not entered or identified accurately in Part 1 of the Deficiency Report, the **QA team** makes appropriate changes to the information and consults with the originator, if appropriate.

Log the deficiency

The **QA team** assigns a number to the Deficiency Report (DR) and enters it into the tracking log or database. A duplicate backup record should be kept.

Deficient items

For deficiencies involving items (typically equipment), the **QA team** contacts the appropriate responsible manager to ensure that the following steps have been taken, as appropriate:

- deficient items are tagged or otherwise labeled with unique identifiers, specific instructions regarding their use, and the DR number that provides the details of the deficient condition(s).
- deficient items are segregated, when practical, or other precautions are taken to prevent their inadvertent use or installation.

Determine responsible team

The **QA team** determines whether the deficiency is applicable to more than one team of the group, and, if only one team, which team is responsible.

IF...	THEN...
deficiency involves more than one project of the group or the group office…	forward to group leader.
deficiency involves only one project of the group…	forward to the project leader.

Evaluation and assignment of responsible individual

Deficiency valid?

The **responsible manager** for the organization in which the deficiency occurred (this is generally the manager of the smallest organizational unit with corrective action responsibility; usually a team leader, project leader, program manager, or group leader) reviews the DR (within two weeks, maximum) and either agrees or does not agree that a violation of a requirement has occurred.

IF...	THEN...
responsible manager agrees…	Check the appropriate box in Part 3, assign a responsible individual, and forward the DR to the responsible individual.
responsible manager does not agree…	Check the appropriate box in Part 3 and return the DR to the QA team.

If there is disagreement about validity

If the Deficiency Report was returned to the QA team because of disagreement, the **QA team** contacts the originator of the DR, subject matter experts, or others (as necessary) to evaluate and decide if the deficiency should be rewritten, clarified, dropped, or resubmitted to the responsible manager.

If there is still disagreement after contacting others, the **QA team** elevates the issue to the group leader, or if necessary, to the division director.

Proposing and evaluating corrective action

Evaluating the deficiency and proposing a corrective action

The individual assigned responsibility (**responsible individual**):

- evaluates the reasons and causes behind the occurrence of the deficiency,
- proposes a corrective action, and
- commits to a deadline by which the corrective actions will be completed.

In some cases, depending on the severity of the deficiency, a root cause analysis should be performed before proposing a corrective action. Assistance in performing a root cause analysis is available from the QA team or other organizational quality professionals.

The **responsible individual** completes Part 4 of the Deficiency Report (attaching additional pages if necessary) and returns the Deficiency Report (within two weeks, maximum) to the QA team.

Evaluating proposed corrective action

The **QA team** evaluates the proposed corrective actions (within two weeks, maximum) to determine if they are reasonable and whether the actions will prevent recurrence of the deficiency. Consult with appropriate technical or subject matter experts.

IF...	THEN...
Proposed corrective actions are reasonable and will prevent recurrence of the deficiency…	Return the DR to the responsible individual for implementation.
Corrective actions do not address deficiency…	Return the DR to the responsible individual with an explanation and instructions to repeat the steps in the block above.

Implementing and verifying corrective action

Performing the corrective actions

The **responsible individual** implements the corrective actions within the time period stated on the Deficiency Report.

If additional time is required, obtain the approval of the QA team. Correct the completion date and obtain the initials of the QA team member on the Deficiency Report.

After the corrective actions are completed, the **responsible individual** enters the completion date in Part 6 and returns the DR to the QA team.

Verification of corrective action

The **QA team** arranges for verification, by either a QA team member, line manager, or other appropriate individual, that the corrective actions were completed as stated in the Deficiency Report. Verification may be completed by examining objective evidence, interviewing individuals, or other means as appropriate to the severity of the deficiency. The verifier signs Part 6.

For deficiencies that were found or initiated by outside organizations (e.g., during external assessments), the **QA team** contacts those organizations if they are to perform the verification. The **verifier** signs Part 6.

Close-out

After verification, the **QA team** forwards the DR to the records coordinator and logs the deficiency as closed.

As a courtesy and to show appreciation for initiating the deficiency, the originator should be notified and informed of the final resolution.

Records resulting from this procedure

Records

The following record generated as a result of this procedure is submitted within two weeks of completion to the group records coordinator:

- Deficiency Report

Click here to record “self-study” training to this procedure.

Air Quality Group

DEFICIENCY REPORT, Page 1 of 2

ESH-17-DR-_____.
This form is from ESH-17-026

Part 1: Any employee

Requirement: _____

_____

_____

_____

_____

_____

Description of deficiency:

_____

_____

_____

_____

_____

SAMPLE

_____ _____ _____
Originator signature | Name (print) | Date

Part 2: QA team

Screen for duplicate, log into database, assign number.

Deficiency is valid? Yes No If No, give reasons: _____

_____

_____

_____

_____ _____ _____
QA team signature | Name (print) | Date

Part 3: Responsible manager: group leader, project leader, team leader, etc.

Agree with deficiency? Yes No If No, give reasons (attach additional page if necess.), return to deficiency coord:

_____

_____

_____

If Yes, assigned to responsible individual: _____. Forward DR to responsible individual.

_____ _____ _____
Responsible manager | Name (print) | Date

Continue on page 2.

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DEFICIENCY REPORT, continued

Part 4: Responsible individual

Cause of deficiency, root cause for severe deficiencies: _____

_____

_____

_____

_____

_____

_____

Proposed corrective actions (attach additional page if necessary): _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

SAMPLE

Corrective actions will be completed by this date: _____.

_____ _____ _____
Responsible individual signature | Name (print) | Date

Part 5: QA team

Approval of proposed corrective actions:

_____ _____ _____
QA team signature | Name (print) | Date

Part 6: Responsible individual

Corrective actions completed on: _____.

_____ _____ _____
Responsible individual signature | Name (print) | Date

Part 7: Verifier

Proper completion of corrective actions verified:

_____ _____ _____
Verifier signature | Name (print) | Date

After this form is completed, submit to the ESH-17 records coordinator.

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DEFICIENCY REPORT, Page 1 of 2

ESH-17-DR-_____.
This form is from ESH-17-026

Part 1: Any employee

Requirement: _____

_____

_____

_____

_____

_____

Description of deficiency:

_____

_____

_____

_____

_____

_____

_____ _____ _____
Originator signature Name (print) Date

Part 2: QA team

Screen for duplicate, log into database, assign number.

Deficiency is valid? Yes No If No, give reasons: _____

_____

_____

_____

_____ _____ _____
QA team signature Name (print) Date

Part 3: Responsible manager: group leader, project leader, team leader, etc.

Agree with deficiency? Yes No If No, give reasons (attach additional page if necess.), return to deficiency coord:

_____

_____

_____

If Yes, assigned to responsible individual: _____. Forward DR to responsible individual.

_____ _____ _____
Responsible manager Name (print) Date

Continue on page 2.

Air Quality Group

DEFICIENCY REPORT, continued

Part 4: Responsible individual

Cause of deficiency, root cause for severe deficiencies: _____

_____

_____

_____

_____

_____

_____

Proposed corrective actions (attach additional page if necessary): _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Corrective actions will be completed by this date: _____.

_____	_____	_____
Responsible individual signature	Name (print)	Date

Part 5: QA team

Approval of proposed corrective actions:

_____	_____	_____
QA team signature	Name (print)	Date

Part 6: Responsible individual

Corrective actions completed on: _____.

_____	_____	_____
Responsible individual signature	Name (print)	Date

Part 7: Verifier

Proper completion of corrective actions verified:

_____	_____	_____
Verifier signature	Name (print)	Date

After this form is completed, submit to the ESH-17 records coordinator.